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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,876	07/20/2001	John Howard Skerritt	Q-64066	5306

7590

07/19/2005

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/830,876

Applicant(s)

SKERRITT, JOHN HOWARD

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5-4-05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The response filed on 04 May 2005 has been received. Claims 1, 3-14 and 23-30 are pending.
2. The rejection of claims 14, 24, 29 and 30 under 35 USC 112, second paragraph is withdrawn in view of Applicant's arguments and/or amendment to the claims.
3. The rejection of claims 1, 3-14, 23 and 25-30 under 35 USC 102 (b) as being anticipated by Sander is withdrawn in view of Applicant's arguments.
4. All rejections not reiterated herein below are withdrawn.

Information Disclosure Statement

5. The information disclosure statement filed 04 May 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112, First Paragraph

6. Claims 25-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

7. Claims 25-29 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for determining the presence or amount of alpha-amylase in a sample, does not reasonably provide enablement for a method for determining weather damage in a plant or crop. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 25 recites a method for determining weather damage in a plant or crop by detecting the presence of alpha-amylase in a sample of the plant or crop. Such a method does not have support in the specification as originally filed. The specification discloses a method for measuring alpha-amylase in a test sample and briefly mentions that alpha amylase is related to preharvest sprouting which could be due to weather damage. However, the specification fails to positively correlate the presence of alpha-amylase to weather damage. Preharvest sprouting could be caused by contamination or storage condition of grain silos that does not involve weather damage, per se.

Furthermore, the specification does not enable a method for determining weather damage in a plant or crop as claimed because no data is presented nor correlations made in the specification as to the amount of alpha-amylase detected and weather damage.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-14 and 23-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LeCommandeur et al., (Hybridoma. Vol. 9, No. 2, 1990, pp. 177-187).

LeCommandeur discloses a sandwich ELISA for barley alpha-amylase using monoclonal antibodies that binds to different epitopes of the alpha-amylase. See page 178, *Materials and Methods*. LeCommandeur teaches the use of an extraction solution comprising malate buffer, CaCl₂ and NaCl at pH 5.2 to prepare an extract from 6-days germinated grains of barley.

Even though LeCommandeur is silent with respect to the epitopes of alpha-amylase to which the antibodies binds are those disclosed as SEQ ID NO. 1, 2 and 3, LeCommandeur does disclose all of the limitation of claim 1 including binding of the antibodies to distinct epitopes of alpha-amylase and since SEQ ID NO. 1, 2 and 3 are deemed to be inherently possessed by the alpha-amylase of the prior art, the claims are anticipated by or, in the alternative, obvious over the teachings of Sanders. See In re Best, Bolton, and Shaw (CCPA) 195 USPQ 430.

Response to Arguments

10. Applicant's arguments filed 04 May 2005 have been fully considered but they are not persuasive.

It is noted that none of the references listed in the IDS dated 04 May 2005 and relied upon for support in the arguments, have been submitted with the IDS. The cover letter suggests that the references will be submitted at a later date, however, to date, they have not been received.

In response to the written description and enablement rejections, Applicant argues that it is not necessary for the specification to demonstrate that alpha amylase in a cereal crop is associated with weather damage as this is well known in the art as of the filing date of the application. Applicant cites Meredith et al in support of this assertion.

This argument is not persuasive. As of the date of this office action, the Meredith reference has not been submitted; therefore, its alleged supports cannot be determined.

The argument that it is well established before the filing date of the instant application that a method for determining the level of alpha amylase in a sample was useful for determining weather damage in a cereal grain or flour is not persuasive. As discussed previously, there is no evidence or written support for this assertion. Grain damage would be due to a number of different factors, one of which may be weather related. The specification only discloses a method for measuring alpha-amylase in a test sample and briefly mentions that alpha amylase is related to preharvest sprouting which could be due to weather damage, it fails to teach a positive or exclusive

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correlation of the presence of alpha-amylase to weather damage. Preharvest sprouting could be caused by contamination or storage condition of grain silos that does not involve weather damage, per se.

Furthermore, the specification does not enable a method for determining weather damage in a plant or crop as claimed because no data is presented nor correlations made in the specification as to the amount of alpha-amylase detected and weather damage.

Applicant argues that it is generally accepted in the art that environmental changes, in particular rain, cause pre-harvest sprouting. Thus, an increase in alpha-amylase levels or activity is a measure of weather damage or sprouting damage in seed crops. This is not persuasive. As stated previously, preharvest sprouting could be caused by reasons other than weather damage. Furthermore, none of the articles supporting Applicant's arguments were submitted; therefore, their alleged support cannot be determined.

Applicant argues that the specification clearly describes methods for detecting alpha-amylase and that the detection of alpha-amylase can be use to determine whether or not the sample comprises pre-harvest sprouted (or weather damaged) cereal.

This is not persuasive. It is noted that the claims are drawn to the assessment of weather damage by detected alpha-amylase in a sample. The rejection of record states that the specification does not provide any data that positive correlates the amount of alpha-amylase to weather damage in crop. Applicant has not provided any evidence to

support the assertion that detection of alpha-amylase in a sample is positively and exclusively correlated to weather damage.

The argument that Lecommandeur does not specifically teach that it's alpha amylase specific monoclonal antibodies binds to either a first or second epitopes comprising one or more amino acid sequences selected from the consisting of SEQ ID NO. 1, 2 and 3 is not persuasive. As stated previously, Lecommandeur teaches that their monoclonal antibodies bind to different epitopes of barley alpha amylases, and the instant invention the detection of alpha amylases from barley. It would appear that the identical analyte is being detected; therefore, the evidence for anticipation, both regarding structure and method of using is overwhelming. It is also noted that the claims recite that the antibody binds to an epitope *comprising* the noted sequence; this does not exclude epitopes that may have overlapping sequences.

Applicant's argument essentially refutes the validity of the reference's conclusion regarding the sequence of the analyte, without providing any support for that argument. However, MPEP § 2112 explicitly states that

[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote

omitted]." The burden of proof is similar to that required with respect to product - by - process claims. Quoting *In re Fitzgerald*, 619 F. 2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (itself quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 - 34 (CCPA 1977)).

Thus, absent some direct evidence that Lecommandeur's disclosure is in error, it is respectfully submitted that the rejection of record must be maintained.

Conclusion

11. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

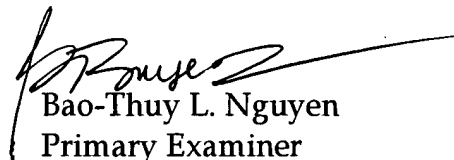
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571)

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272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
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7/13/05